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WEATHERBY, ELLSWORTH				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/799,094

Applicant(s)

WANG ET AL.

Examiner

ELLSWORTH WEATHERBY

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 24, 27, 28, 30, 46, 48, 53, 60, 61, and 64 are objected to because of the following informalities: Claims 24 and 28 are objected to because the materials list appears to be claiming all the materials from the list. Claim 27 includes improper Markush language. Claims 30,46,60,61 and 64 are objected to because it is unclear what structural has been set forth. Dependant Claims 35, 48, and 53 are objected to because independent Claim 1 has been amended to set forth a *marker band* rather than a *marker* However, in several dependant claims, the Applicant refers to a marker. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7, 9, 23-34, 36-44, 46-47, 54-59, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (Pub. No.: 2004/0193140) in view of Gellman et al. (USPN 7,001,341 B2).

Griffin et al. '140 (hereinafter Griffin) teaches a medical device, comprising: a tubular body made of any polymer body including polymers and metals [0029]; a

radiopaque or MR-visible marker band, coil, or ring may be incorporated within or disposed about a portion of the body [0056-0057]. The marker band is attachable using suitable techniques such as adhesive bonding, crimping, friction fitting, mechanically fitting, chemically bonding, thermally bonding, welding (e.g., resistance, RF, or laser welding), soldering, brazing, or the use of a connector member or material, or the like, or combinations thereof [0056]. Griffin also teaches that imagable materials may include tungsten, gold, platinum, Elgiloy, MP35N, nitinol, polymer embedded with said the like, and others [0031; 0033]. Griffin also teaches that the invention may be applied to a balloon catheters, guidewires, and stents [0020; 0027]. Griffin also teaches that the marker may include multiple layers [0028; 0033].

Griffin teaches using multiple imaging modalities to including MRI and X-ray [0033]. However, Griffin does not expressly teach that the attached marker bands or rings are detectable by multiple imaging modalities. Griffin also does not expressly teach that the fluoroscopic imaging enhancement material and MRI enhancement material are in separate concentric and noncircumferentially contiguous layers. Griffin teaches varying the thickness of the markers to achieve desired characteristics [0033], however does not expressly teach that the MRI material has a magnetic susceptibility of about 500.times.10.sup.-6 Emu or greater.

Gellman et al. '341 (hereinafter Gellman) teaches separate concentric and noncircumferentially contiguous marker bands disposed about an internal medical device, where each of the bands or separate layers of the bands can be differentiated by multiple diagnostic techniques such as ultrasound, MRI, and X-ray fluoroscopy (col.

4, l. 56- col. 5, l. 20). Gellman et al. '341 also teaches the use of MRI bands having various magnetic susceptibilities (col. 4, l. 56- col. 5, l. 20). Gellman et al. '341 also teaches that the marker may include multiple layers (col. 4, ll. 61-64).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Griffin in view of Gellman. The motivation to modify Griffin in view of Gellman would have been to differentiate between multiple devices using a supply of markers, which may be unique in their imagable composition or positioning such that each device can be readily distinguished, as taught by Gellman (col. 4, l. 56- col. 5, l. 20).

4. Claims 8, 10-11, 13-16, 48-50 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (Pub. No.: 2004/0193140) in view of Gellman et al. (USPN 7,001,341 B2) as applied to claims 1 and 39 above, and further in view of Aita et al. (USPN 6,884,234 B2).

Griffin in view of Gellman teaches all the limitations of the claimed invention except for expressly teaching that the layers have a thickness of about 0.005 inch or less. Griffin in view of Gellman also do not expressly teach that the marker band includes three or more layers. Griffin in view of Gellman also do not expressly teach that a first layer includes a fluoroscopic imaging enhancement material and a second layer has a MRI enhancement material and a third layer. Griffin in view of Gellman also do not expressly teach that the third layer is in contact with the biocompatible body. Griffin in view of Gellman also do not expressly teach that the third layer is between the first

and second layers. Griffin in view of Gellman also do not expressly teach that the third layer defines an exterior surface of the marker.

In the same field of endeavor, Aita et al. '234 (hereinafter Aita) teaches a plurality of layers where separate layers are provided for each imaging enhancement material (col. 3, ll. 1-13). Aita further teaches that a third layer that acts as a spacer between the first and second layers (col. 3, lines 1-13). Aita goes on, teaching a plurality of imaging layer combinations (col. 3, l. 14- col. 4, l. 4). Aita also teaches that the imageable layers should have a thickness of about .0005 inch to 0.01 inch (col. 3, ll. 1-13). Aita also provides a plurality of imageable layers disposed between outer and inner layers (col. 4, l. 65- col. 5, l. 11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Griffin in view of Gellman with Aita. The motivation to modify Griffin in view of Gellman with Aita would have been to enhance the mechanical characteristics of the device, as taught by Aita (col. 5, ll. 3-11).

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (Pub. No.: 2004/0193140) in view of Gellman et al. (USPN 7,001,341 B2) as applied to claim 1 and above, and further in view of Devens et al. (Pub. No.: 2005/0124976).

Griffin in view of Gellman teaches all the limitations of the claimed invention except for expressly teaching that that the marker includes a drug layer.

In the same field of endeavor, Devens et al. '976 (hereinafter Devens) teaches a plurality of internal medical devices comprising fluoroscopic and MRI markers in one or

more separate layers [0062]. Devens also teaches an innermost third layer in contact with the catheter body [0008]. Devens also teaches that the biocompatible body can be formed into a stent (claim 42). Devens also teaches a bonding layer [0007] and a drug delivery layer [0061].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Griffin in view of Gellman with Devens. The motivation to modify Griffin in view of Gellman with Devens would have been to provide multiple functions for each band using well known multiple layered medical devices, as shown by Devens.

6. Claims 17-18, 21-22, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (Pub. No.: 2004/0193140) in view of Gellman et al. (USPN 7,001,341 B2) as applied to claims 1 and 54 above, and further in view of Dor et al. (USPN 6,334,871 B1).

Griffin in view of Gellman teaches all the limitations of the claimed invention except for expressly teaching that the MRI imaging enhancement material has a radiopacity of 0.9 or less than the radiopacity of steel and that the MRI enhancement material has an atomic number of 40 or less. Griffin in view of Gellman also do not expressly teach that the radiopacity is about 1.1 times more than stainless steel. Griffin in view of Gellman also do not expressly teach that the MRI visibility is greater than about 280mg/ml gadodiamine in 5000 ml blood.

In the same field of endeavor, Dor et al. '871 (hereinafter Dor) teaches using a material with radiopacity similar to steel to enhance or decrease radiopacity compared

steel (claim 1, claim 5). Dor also teaches using a cobalt-chromium alloy (claim 13). Regarding claim 22, the examiner is interpreting the limitations of the claim to be met because Dor claims several relative visibilities and it is obvious variation to determine the visibility of device relative to any available and well-known medical product including having a visibility about equal or greater than about 280 mg/ml gadodiamine in 5000 ml blood.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Griffin in view of Gellman with Dor. The motivation to modify Griffin in view of Gellman with Dor would have been to use a material in varying thickness that would have less radiopacity than steel to improve imaging or visibility of the device.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (Pub. No.: 2004/0193140) in view of Gellman et al. (USPN 7,001,341 B2) and Dor et al. (USPN 6,334,871 B1) as applied to claim 17 above, and further in view of MacDonald et al. (Pub. No.: 2007/0093142).

Griffin in view of Gellman and Dor teaches all the limitations of the claimed invention except for expressly teaching that the marker includes multiple layers and wherein the layers have a thickness of about 1 micron or less.

In the same field of endeavor, MacDonald et al. '142 teaches coating a ring or a catheter with a layer that has a thickness of about 1 micron or less [0175].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Griffin in view of Gellman and Dor with MacDonald et al. '142. The

motivation to modify Griffin in view of Gellman and Dor with MacDonald et al. '142 would have been to minimize the layer's interaction with the surrounding environment, as taught by MacDonald et al. '142 [0175].

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (Pub. No.: 2004/0193140) in view of Gellman et al. (USPN 7,001,341 B2) as applied to claim 1 above, and further in view of MacDonald et al. (Pub. No.: 2007/0093142).

Griffin in view of Gellman teaches all the limitations of the claimed invention except for expressly teaching that the marker includes multiple layers and wherein the layers have a thickness of about 0.005 inch or less. Griffin in view of Gellman also do not expressly teach that the MRI enhancement material is present at 25% or less by weight of fluoroscopic imaging enhancement material.

In the same field of endeavor, MacDonald et al. '142 (hereinafter MacDonald) teaches facilitating MRI compatibility of a device by minimizing the amount of coated MRI enhancing material where the coating layer that has a thickness of about 1 micron or less [0175].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Griffin in view of Gellman with MacDonald et al. '142. The motivation to modify Griffin in view of Gellman with MacDonald et al. '142 would have been to minimize the layer's interaction with the surrounding environment, as taught by MacDonald et al. '142 [0175].

9. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (Pub. No.: 2004/0193140) in view of Gellman et al. (USPN 7,001,341 B2) as applied to claim 34 above, and further in view of Lee et al. (Pub. No.: 2005/0215885 A1).

Griffin in view of Gellman teaches all the limitations of the claimed invention except for expressly teaching that the markers are indicative of the location of a balloon carried by the balloon catheter.

In the same field of endeavor, Lee et al. '885 teaches a visualizing a balloon on an MRI visible balloon catheter by using several spaced markers (fig. 3; 0010).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Griffin in view of Gellman with Lee et al. '885. The motivation to modify Griffin in view of Gellman with Lee et al. '885 would have been to provide a facilitate imaging and/or placement of a balloon catheter.

10. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (Pub. No.: 2004/0193140) in view of Gellman et al. (USPN 7,001,341 B2) as applied to claim 43 above, and further in view of Kucharczyk et al. (USPN 6,026,316).

Griffin in view of Gellman teaches all the limitations of the claimed invention except for expressly teaching that the MRI enhancement material is disposed within a ceramic matrix.

Kucharczyk et al. '316 (hereinafter Kucharczyk) teaches using MR visible ceramics in a catheter (col. 4, lines 16-35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Griffin in view of Gellman with Kucharczyk et al. '316 to facilitate the use of device in the presence of strong MRI fields.

11. Claims 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (Pub. No.: 2004/0193140) in view of Gellman et al. (USPN 7,001,341 B2) and Aita et al. (USPN 6,884,234 B2) as applied to claim 48 above, and further in view of Devens et al. (Pub. No.: 2005/0124976).

Griffin in view of Gellman and Aita teaches all the limitations of the claimed invention except for expressly teaching that the marker a bonding layer and a drug layer.

In the same field of endeavor, Devens teaches a plurality of internal medical devices comprising fluoroscopic and MRI markers in one or more separate layers [0062]. Devens also teaches a bonding layer [0007] and a drug delivery layer [0061].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Griffin in view of Gellman with Devens. The motivation to modify Griffin in view of Gellman with Devens would have been to provide multiple functions for each band using well known multiple layered medical devices, as shown by Devens.

12. Claims 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (Pub. No.: 2004/0193140) in view of Gellman et al. (USPN 7,001,341 B2)

as applied to claims 1, 39 and 54 above, and further in view of Ishii (Pub. No.: 2003/0163117).

Griffin in view of Gellman teaches all the limitations of the claimed invention except for expressly teaching that the marker is C-shaped.

In the same field of endeavor, Ishii '117 (hereinafter Ishii) teaches using C-shaped markers [0082].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Griffin in view of Gellman with Ishii. The motivation to modify Griffin in view of Gellman with Ishii would have been to use any known marker shape to facilitate secure attachment to the medical device.

Response to Arguments

13. Applicant's arguments, see page 10/17, filed 12/20/2007, with respect to the 112 2nd paragraph rejections have been fully considered and are persuasive. The 112 2nd paragraph rejections of claims 17, 32, 22 and 60 have been withdrawn.

14. Applicant's arguments with respect to claims 1-64 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ELLSWORTH WEATHERBY** whose telephone number is (571) 272-2248. The examiner can normally be reached on **M-F 8:30 a.m. - 5:00 p.m.**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

EW